

EXHIBIT 27

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EXPERT REPORT

**Analysis of Distributor and Manufacturer
Regulatory Compliance to Maintain
Effective Controls for the Prevention of
Diversion of Controlled Substances**

Prepared by

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D. ARCOS/DADS

The Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS)¹⁸ system is used to track and report the transfer of pharmaceuticals and to detect potential diversion. This system of records is maintained pursuant to the reporting requirements of the Comprehensive Drug Abuse Prevention and Control Act of 1970¹⁹ and to fulfill the United States treaty obligations under the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances of 1971.²⁰

The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispenser level.²¹

The information contained in the ARCOS system consists of documentation of individual business transactions between individuals who handle controlled substances at every level, from manufacturers down to the pharmacies. Records include copies of controlled substances inventories, drug codes, deletion and adjustment reports, sales, and purchase orders, and includes, but not limited to the date of the transaction, the name, quantity, and quality of the chemicals/substances purchased or dispensed, the parties to the transaction, NCD code, and the DEA registrant numbers. This information provides an audit trail of all manufactured and/or imported controlled substances.

All automated data files associated with ARCOS/DADS are maintained in the Department of Justice Data Center and the Drug Enforcement Administration Data Center and the system is

¹⁸ "ARCOS" refers to the automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions. Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV psychotropic drugs (manufacturers only). ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States (U.S.) by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts. See United States Department of Justice, Drug Enforcement Administration, Diversion Control Division, Automation of Reports and Consolidated Orders System (ARCOS), *Background: What is ARCOS and What Does it Do?*, <https://www.deadiversion.usdoj.gov/arcos/#background> (last visited September 7, 2017).

¹⁹ (21 U.S.C. 826(d))

²⁰ 69 FR 51104-02.

²¹ See ARCOS Registrant Handbook, United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Section 1.1.1, *ARCOS Defined* (Version 1.0 August 1997).

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located at Drug Enforcement Administration, 700 Army Navy Drive, Arlington, VA 22202. 69 FR 51104-02.

The ARCOS/DADS system uniquely has access to *all* of the data submitted by each DEA registrant from the across the country.²² These distribution transactional records are compiled by the DEA through a portal and the data is compiled by DEA in accordance with law for determining quota, distribution trends, internal audits, inspection, investigations and other analyses.²³ Additionally, the DEA provides internet access to summary data from this system.

The DOJ/DEA disclosed the national ARCOS database to the Plaintiffs' Executive Committee (2006-2014) and that additional transactional data was independently disclosed by some of the defendants. Both sets of data were then uploaded to a database managed by Craig J. McCann, PhD, CF, of Securities Litigation and Consulting Group, Inc. ("SLCG") (retained as an expert by the PEC). I have relied upon data derived from and provided by SLCG in the formulating of specific requests.

The ARCOS data, defendant transactional data, and the SLCG reports generated therefrom are consistent with the types of data, facts, information, and reports I would typically rely on in conducting the analysis and reaching the opinions contained herein. I am very familiar with the ARCOS data and defendant transactional data and have experience analyzing the data and reports generated therefrom. I have reviewed SLCG's methods and reports and they are consistent with my understanding, based on my experience, of how the data should be analyzed.

E. DEA DIVERSION INVESTIGATOR'S MANUAL.

The DEA published a manual which provides further guidance related to the statutory and regulatory duties. Portions of the manual have previously been publicly available and accurately set forth the charge for DEA investigator as follows:

Registrants, who routinely report suspicious orders, yet fill these orders, with reason to believe they are destined for the illicit market, are expressing an attitude of irresponsibility that is a detriment to the public health and safety as set forth in 21 U.S.C. 823 and 824. Suspicious orders include those which are in excess of legitimate medical use or exhibit characteristics leading to possible diversion such as: orders of unusual size, unusual frequency, or those deviating substantially from a normal pattern. *The supplier can determine whether the order is excessive by checking their own sales and establishing the average amount of controlled substances shipped to registrants of the same apparent size in a particular geographic area. If the customer exceeds this threshold, the request should be viewed as suspicious. This activity, over extended periods of time, would lead a reasonable person to believe that controlled substances possibly are being diverted.* An

²² The DEA maintains the Automation of Reports and Consolidated Orders System ("ARCOS"), an official automated comprehensive drug reporting system that monitors the flow of DEA controlled substances from their point of manufacture through commercial channels to the point of sale or distribution at the dispensing/retail level. Drug wholesalers do not have access to the ARCOS data or to the data of other wholesalers and distributors. *Keysource Med., Inc. v. Holder*, No. 1:11-CV-393, 2011 WL 3608097, at *2 (S.D. Ohio Aug. 16, 2011).

²³ https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html

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- The documentation of due diligence performed and the results thereof being retained
- Suspicious orders also being reported to states where applicable.
- Suspicious orders being reported as drug families and by individual drugs.
- Sufficient training and education for all involved in the distribution of controlled substances.

Almost as essential as the due diligence being conducted is that efforts made to dispel suspicions and the results thereof are adequately documented and retained. Thorough recordkeeping and documentation of the steps taken to justify flagged orders are necessary not only to explain why decisions were made in any particular instance, but also to inform future decisions regarding flagged orders. One important aspect of every due diligence review should always be an examination of the historical transactions of the customer who placed the flagged order. Such an examination is necessary to evaluate trends over time and to inform decisions about whether or not orders of controlled substances are likely to be diverted into illicit channels. For purposes of conducting a historical review of a customer when evaluating a flagged order, if prior due diligence investigations are not adequately documented and retained, they may as well have not occurred at all.

As explained above, the goal of suspicious order monitoring is to ensure that bulk orders of controlled substances are being shipped for legitimate purposes rather than being diverted for illicit purposes. A suspicious order monitoring system has a self-policing aspect with the twin aims of both stopping the shipment of orders at risk of diversion and investigating those who have placed orders that are identified as suspicious. Not shipping a suspicious order is only part of the equation. The other parts are investigating the buyer and the circumstances surrounding the order and, if necessary, reporting the suspicious order to the DEA. Any order that is suspicious requires action to dispel suspicion and confirm legitimacy. Otherwise the order should not ship. When a distributor neglects to dispel suspicion and ships anyway, the risk of diversion does not disappear when the order ships. For this reason, any future order or shipment to that particular pharmacy or buyer should not ship until an investigation of the initial suspicious order occurs because there is an outstanding concern about the past shipment that has not been addressed. Otherwise, a distributor is potentially sending larger and larger quantities of controlled substances to a buyer that is under suspicion of being a diversion risk. The suspicious order monitoring system failures described above directly led to massive quantities of pills being shipped to buyers who had placed suspicious orders of controlled substances. These orders never should have shipped until after the suspicion of diversion was dispelled.

III. Identifying Suspicious Orders Distributed in CT1

I have described in this report the ways in which distributor and manufacturer defendants' inadequate response to their statutory and regulatory requirements to maintain effective controls related to the sales of prescription opioids would potentially cause the diversion of these pills for non-medical use. I have reviewed five suspicious order methodologies, some of which were

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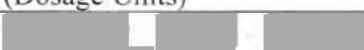
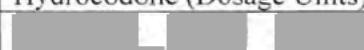
utilized by one or more of the defendants. These methodologies are identified in the McCann Report as "Maximum Monthly, Trailing 6 Month Threshold," "2x Trailing 12 Month average," "Extraordinary Order Method – 3x Trailing 12 Month Average," "Maximum 8,000 Dosage Units Monthly," and "Maximum Daily Dosage Units." The purpose of each system was to identify suspicious orders that should not be shipped unless the distributors' due diligence eliminated the suspicion of diversion. Each method would have identified a significant volume of orders of opiates as shown in the tables below.¹¹⁰

A. Methodology: Maximum Monthly, Trailing 6 Month Threshold

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug (p. 46)		
Cardinal (p. 91)		
McKesson Corporation (p. 136)		
CVS (p. 181)		
Walgreens (p. 236)		

Summit County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug (p. 676)		
Cardinal (p. 721)		
McKesson Corporation (p. 766)		
CVS (p. 811)		
Walgreens (p. 236)		

¹¹⁰ I utilized these Defendants: Cardinal Health, AmerisourceBergen Drug, McKesson, Walgreens, and CVS as they constitute a significant majority of the opioid pills delivered into CT1 according to the data described in the Expert Report of Craig J. McCann, Ph.D., CFA, App. 9, pp. 3775 and 3845.

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McKesson Corporation ¹⁴⁸	[REDACTED]	[REDACTED]	[REDACTED]
CVS ¹⁴⁹	[REDACTED]	[REDACTED]	[REDACTED]
Walgreens ¹⁵⁰	[REDACTED]	[REDACTED]	[REDACTED]

I have been asked to identify the number of opioid pills that entered Cuyahoga and Summit Counties unlawfully. This is an impossible task due to the defendants' failure to comply with their Federal statutory and regulatory requirements.¹⁵¹ However, it is my opinion to a reasonable degree of professional certainty that applying the test set forth in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (2017) provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size.¹⁵² See Methodology A above. Pursuant to *Masters*, "as a matter of common sense and ordinary language, orders that deviate from a six-month trend are an 'unusual' and not 'normal' occurrence" *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 216 (D.C. Cir. 2017). I say this understanding that this litigation will be advanced by selecting a methodology quantifying a volume of pills that entered CT1 jurisdictions unlawfully and providing this data to an economist to measure the harm caused by this volume.

Based on my education, background, and experience, as well as my review of relevant documents, the absence of adequate distributor due diligence and failure to respond to indicators of suspicious orders as described in this report constitutes the Defendants' failures to comply with the requirements of the Controlled Substances Act. It is further my opinion that this misconduct led to the excess quantity of opiate pills flooding the illicit market in CT1 jurisdictions.

IV. REGISTRANT SUSPICIOUS ORDER MONITORING SYSTEMS (SOMS)

I have been asked to review the documents produced in this litigation to determine whether the distributors complied with the statutory and regulatory duties outlined above. In this process I have reviewed numerous documents and depositions for each of the enumerated Defendants. Based on my review it is my opinion to a reasonable degree of professional certainty that each of the distributors failed to comply with their statutory and regulatory duty to maintain effective controls to prevent diversion and to design and operate a system to identify and report suspicious orders.

¹⁴⁸ *Id.* at 802.

¹⁴⁹ *Id.* at 847.

¹⁵⁰ *Id.* at 892.

¹⁵¹ This includes, but is not limited to, the requirement of the defendants to maintain effective controls against diversion, the reporting requirement, and the not shipping requirement. The detail of some of these failures is set out more completely below in the distributor and manufacturer specific sections of this report.

¹⁵² This approach does not take into consideration unusual pattern or frequency.

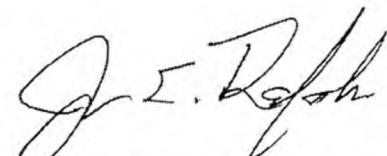
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respect to the SOMs policies at Insys. However, Mr. Reimer's deposition has been stayed until after the criminal trial by the DOJ in the District of Massachusetts because Mr. Reimer is on the DOJ's witness list.

4. Nevertheless, deposition testimony by current Insys employees has confirmed that Insys failed to implement any SOM system or maintain any SOM protocols until 2018.⁹⁰⁸
5. This failure to conduct any sort of SOM process continued despite the fact that Insys was conscious that it habitually lost track of inventory in its downstream customers like Linden Care.⁹⁰⁹ For other wholesalers where they did not receive inventory level reports, Insys estimated the levels. Significant differences between actual and estimated inventory levels often resulted. Many times, distributor purchases exceeded customer demand, a situation that creates a risk of diversion.

In my expert opinion, Insys failed to conduct any SOM process, even failing to track for orders of unusual size. The lack of any SOM program did not satisfy DEA requirements to detect and investigate suspicious orders. Insys failed to maintain effective controls to prevent diversion.

I reserve the right to amend or supplement my opinions in this matter considering any new or additional information.



James E. Rafalski

Date: April 15, 2019

⁹⁰⁸ See Deposition of James Doroz at 53; 118; 251. See also Thomas Uidious Tr. at 19; 44.

⁹⁰⁹ See James Doroz Tr. at 221.